

- Information should be presented in a way that is understandable to the child.
- Researchers should use age-appropriate language, concepts, and methods.

4. **Parental Permission and Child's Assent:**

- Parental or guardian permission is also required alongside the child's assent.
- The child's willingness to participate should be respected, even if it conflicts with the parent's decision.

5. **Assessment of Understanding:**

- Researchers should assess the child's understanding of the research.
- This includes understanding the nature of the research, what it involves, potential risks and benefits, and the voluntary nature of participation.

6. **Voluntariness:**

- Assent must be given voluntarily, without coercion or undue influence.
- Children should know they can withdraw from the study at any time without penalty.

7. **Documentation of Assent:**

- The process of obtaining assent should be documented.
- Depending on the child's age and the study's nature, this might not require a written form.

8. **Ethical Considerations:**

- Researchers must respect the evolving capacities of children.
- They should involve children in decision-making processes in a manner commensurate with their capabilities.

9. **Exceptions to Assent:**

- In certain cases, assent may not be required, such as when the child is not capable of providing assent due to age, maturity, or psychological state.

- In emergency situations, when immediate treatment is necessary and waiting for assent could be harmful, assent may be waived.

10. **Role of Institutional Review Boards (IRBs):**

- IRBs play a crucial role in ensuring the ethical conduct of research involving children.
- They review the assent process to ensure it is appropriate and respectful of children's rights and welfare.

Q: Gift authorship and ghost authorship

- ❖ Gift authorship and ghost authorship are two unethical practices in academic publishing
- ❖ They undermine the integrity of the research process and can have significant implications for the credibility of scientific literature
- ❖ Both, gift and ghost authorships are serious ethical violations in academic publishing
- ❖ They compromise the integrity of the scientific record and can mislead readers and researchers about the origins and credibility of research findings
- ❖ Addressing these issues requires concerted efforts from individual researchers, academic institutions, and publishers.

Gift Authorship

- **Definition:**
 - Gift authorship, also known as honorary or courtesy authorship, occurs when an individual is given authorship credit despite not having made a substantial contribution to the research or the manuscript.
- **Common Reasons:**
 - To curry favor with senior colleagues or superiors.
 - As a gesture of respect or gratitude.
 - To add perceived weight to the paper through a well-known name.
- **Criteria for Authorship:**
 - Ethical guidelines, such as those from the International Committee of Medical Journal Editors (ICMJE), specify that authorship should be based

on significant contributions to the conception, design, execution, or interpretation of the research, drafting or revising the article critically for important intellectual content, and final approval of the version to be published.

- **Implications:**

- Dilutes the credit given to those who actually did the work.
- Can mislead readers about the true sources of research and ideas.
- Potentially involves individuals in any controversy or issues arising from the research without their having had a role in it.

Ghost Authorship

- **Definition:**

- Ghost authorship occurs when someone makes a substantial contribution to a research project or manuscript but is not credited as an author.

- **Common Scenarios:**

- When a professional writer or researcher contributes significantly but is not listed due to the desire to mask involvement from pharmaceutical companies or other entities.
- When junior researchers contribute significantly but are excluded from authorship.

- **Ethical Concerns:**

- Lack of transparency and accountability.
- The true origins and influences on the research are hidden, which can be particularly concerning in clinical research influenced by pharmaceutical companies.
- Can lead to a lack of responsibility for the content.

- **Addressing the Issue:**

- Journals increasingly require authors to specify the contribution of each person listed as an author.
- Some journals also require disclosure of contributions of non-listed individuals.

Comparison and Contrast

- **Visibility:** Gift authorship adds non-contributing authors, while ghost authorship hides the contribution of significant participants.
- **Motivation:** Gift authorship is often motivated by a desire to honor or appease colleagues, whereas ghost authorship can be motivated by a desire to lend undue credibility or hide potential conflicts of interest.
- **Impact on Research Integrity:** Both practices distort the true contribution to research, but ghost authorship also raises concerns about hidden biases and influences.

Addressing the Issues

- **Awareness and Education:** Increasing awareness about the ethical standards of authorship in the academic community.
- **Institutional Policies:** Development and enforcement of clear policies regarding authorship criteria.
- **Journal Requirements:** Journals should enforce strict guidelines requiring disclosure of each author's contribution and acknowledgment of non-listed contributors.

Q: Robust quality criteria

- ✚ In medical research, robust quality criteria are essential to ensure the reliability, validity, and generalizability of study findings. These criteria are critical in evaluating the strength of evidence and in guiding clinical decision-making.
- ✚ Robust quality criteria in medical research are pivotal in ensuring that the findings are credible, ethically sound, and applicable to patient care. Adherence to these criteria strengthens the evidence base that informs clinical practice and healthcare policy.

1. Study Design

- **Randomization:** Reduces bias by equally distributing known and unknown factors among groups in clinical trials.
- **Control Group:** Essential for comparing the intervention's effect.

- **Blinding:** Minimizes bias by preventing the knowledge of treatment allocation from influencing the outcome assessment or treatment.

2. Sample Size and Power

- **Adequate Sample Size:** Ensures sufficient power to detect a clinically significant effect.
- **Power Analysis:** Conducted to determine the minimum sample size needed based on expected effect size and variance.

3. Data Quality and Management

- **Data Accuracy and Consistency:** Rigorous data collection and entry processes.
- **Data Monitoring:** Regular checks for data integrity and completeness.

4. Ethical Considerations

- **Informed Consent:** Ensuring participants are fully informed about the study's risks and benefits.
- **Ethical Approval:** Obtained from relevant institutional review boards or ethics committees.

5. Outcome Measures

- **Valid and Reliable Measures:** Use of standardized, validated tools for outcome assessment.
- **Primary and Secondary Outcomes:** Clearly defined and relevant to the study objectives.

6. Statistical Analysis

- **Appropriate Statistical Methods:** Matching the analysis techniques to the study design and data type.
- **Handling of Missing Data:** Addressing missing data appropriately to avoid bias.
- **Adjustment for Confounders:** Using statistical methods to control for potential confounding variables.

7. Reporting Standards

- **Transparent Reporting:** Following guidelines like CONSORT for trials or STROBE for observational studies.

- **Disclosure of Conflicts of Interest:** Transparency about potential biases due to financial or other interests.

8. External Validity

- **Generalizability:** Assessing whether the study findings are applicable to a broader population.
- **Real-world Relevance:** Ensuring the study context and population reflect real clinical scenarios.

9. Replicability

- **Reproducibility of Results:** Ability of other researchers to replicate findings under similar conditions.

10. Peer Review and Publication

- **Critical Review:** Undergoing rigorous peer review before publication.
- **Publication in Reputable Journals:** Ensures a wider and more critical audience.

Quality Criteria	Description and Importance
Study Design	Incorporates randomization, control groups, and blinding to reduce bias and enhance reliability.
Sample Size and Power	Ensures sufficient sample size for statistical power to detect significant effects. Involves power analysis.
Data Quality and Management	Focuses on accuracy, consistency, and regular monitoring of data.
Ethical Considerations	Includes informed consent and ethical approval to uphold research integrity and participant safety.
Outcome Measures	Utilizes valid and reliable tools for assessing primary and secondary outcomes.
Statistical Analysis	Employs appropriate methods, addresses missing data, and adjusts for confounders to ensure accurate results.
Reporting Standards	Adheres to guidelines like CONSORT or STROBE for transparent reporting and disclosure of conflicts of interest.
External Validity	Assesses the generalizability and real-world relevance of the study findings.
Replicability	Ensures that the study results can be replicated under similar conditions by other researchers.

Peer Review and Publication

Involves critical review and publication in reputable journals for wider scrutiny and acceptance.

